



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

28 May 2004

Charles J. Ganley, M.D.
Director, Division of OTC Drug Products,
Office of Drug Evaluation V
Center for Drug Evaluation & Research
Food and Drug Administration
5600 Fishers Lane (HFD-560)
Rockville, MD 20857

RE: Docket No. 81N-0033

Dear Dr. Ganley:

Reference is made to our letter dated 25 March 2004 in which we requested a feedback meeting to discuss proposed labeling and clinical data in support of OTC monograph status for benzocaine-containing products for the temporary relief of toothache. Reference is also made to your letter dated 29 October 2002 in which the Division of OTC Drug Products and the Division of Dermatologic and Dental Drug Products responded to our proposed research program on benzocaine for temporary relief of pain due to toothache (letter dated 21 June 2002).

As noted in my conversation with Ms. Elaine Abraham, a meeting has been scheduled for 28 June 2004 from 1:30 p.m. to 3:00 p.m. in conference room South 400 at 9201 Corporate Boulevard.

In preparation for this meeting, please find enclosed the following information:

- 1) A list of our meeting attendees (Attachment I)
- 2) Questions we would like the Agency to address during the meeting (Attachment II)
- 3) CHPA Benzocaine Task Group perspective on the questions (Attachment III)

81N-0033

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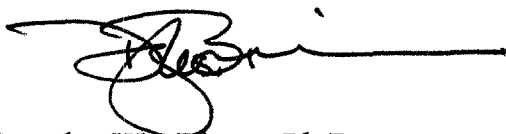
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The following appendices are contained in the briefing package:

- Appendix I: Proposed OTC Monograph Labeling for Benzocaine-Containing Products for the Temporary Relief of Toothache Pain
- Appendix II: Clinical Study BZ-03-08: Topical Benzocaine for the Temporary Relief of Toothache Pain
- Appendix III: Review of the FDA Adverse Experience Reporting System and Spontaneous Reporting System Databases
- Appendix IV: Methemoglobinemia and Topical Benzocaine Use Review and Expert Opinion by: Elliot V. Hersh, DMD, MS, PhD
- Appendix V: Benzocaine Gel Toothache Dose-response Study: Draft Protocol

We look forward to meeting with you on 28 June 2004. Please do not hesitate to contact me at 202-429-3535 should you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Bierer', with a long horizontal line extending to the right.

Douglas Ws. Bierer, Ph.D.
Vice President, Regulatory and Scientific Affairs

cc: Elaine G. Abraham (HFD-560)



*Producers of Quality
Nonprescription Medicines and
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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

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DATE:

6/9/04

TO:

Latroy Tinch

FROM:

Dr. Doug Bierer

NUMBER OF PAGES:

1

(including this cover page)

MESSAGE:

This responds to your inquiry of whether the information marked "CONFIDENTIAL" in Appendices II and V submitted to Docket No. 81N-0033 can be released to the public. We have reviewed this information and have concluded that the information marked "CONFIDENTIAL" in Appendix II (Clinical Study BZ-03-08: Topical Benzocaine for the Temporary Relief of Toothache Pain – Final Report) and Appendix V (Benzocaine Gel Toothache Dose-Response Study: Draft Protocol) may be released to the public.

If there is a transmission problem, please contact

at 202-429-9260.